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## Additives Shouldn't Harm' Even One in Million

PART OF THE confusion about the "safety" of food additives and other environmental risks is the gap between statistics and law.

The 1958 (Delaney) revision of the Food, Drug and Cosmetic Act required that a food additive be tested and found "safe" for human consumption before it could be certified for sale. "Safe" has never been legally defined, however, and its interpretation is left to the discretion of the Secretary of Health, Education and Welfare.

The act does make one restriction: that nothing can be called safe if it causes cancer on feeding to any animal. Theoretical objections can be raised against this principle, but it has had the practical effect of forcing administrative actions in doubtful circumstances where the public was bearing the risks of the uncertainty.

For example, there is no proof at this time that cyclamate causes cancer in man. However, industrial chemicals like naphthylamine that are well known to cause human bladder cancer have a latent period averaging 15 years before they show their effect. Were we to wait another decade before pushing

back on cyclamate (which produces cyclohexylamine in the body), we might be committing a million Americans to bladder cancer while this massive "clinical trial" was going on.

IT IS ALSO true that the Delaney clause might be invoked against essential dietary constituents that could cause cancer in animals in very high doses. In fact, these may have something to do with an irreducible burden of cancer that arises as a by-product of normal metabolism. However, cyclamate is quite dispensable, and it is folly to take such risks with it.

The Delaney clause could indeed be modified for greater scientific precision. New agents should be tested for mutations and congenital malformations as well as cancer. As we develop better theories of and experimental models for other chronic diseases like hypertension and atherosclerosis, these should also be covered. Cancer has taken first place in this list mainly because we already have well-established animal tests for it.

On the other hand, if a quantitative meaning can be attached to ideas like "zero tolerance" and "safety," we might make the law more flexible. Cancer in an animal should be taken as a grave presumption of a hazard for man, but not a final proof of it. It is also true that every mouthful of food that any American eats in the next century will contain at least one molecule of DDT, so that "zero tolerance," taken literally, would be absurd.

THE LAW must set firm standards of expected safety as a logical basis of the tests that attempt to show whether the standard is met. An additive surely should not harm as many as one per million of its innocent users. This standard would be regarded as criminally lax if we knew that 200 Americans a year were being killed. On the other hand, it is very difficult to get advance assurance about any additive with such precision.

We can do experiments in animals with high doses to look for possible trouble. We can investigate the biochemical mechanism of action. We can try to find the formula that governs the relationship of effect to dose. If there is a presumption of hazard, we might still reply

to it and set tolerances for human use—but only if there is a convincing argument that they meet the safety standard.

HEW Secretary Robert H. Finch has announced the relaxation of his categorical ban on cyclamate. The current state of research puts cyclamate, as commonly used, far above the one-per-million standard, but much more work would be needed to understand the exact dimensions of the hazard. If another standard of safety underlies these administrative judgments, this is a number that ought to be advertised on the labels.

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